

S/N 10/787,045

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John D. Hatlestad et al.	Examiner:	Sheetal Rangrej
Serial No.:	10/787,045	Group Art Unit:	3686
Filed:	February 25, 2004	Docket:	279.B27US1
Title:	ADVANCED PATIENT AND MEDICATION THERAPY MANAGEMENT SYSTEM AND METHOD		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Appellant requests review of the Final Rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. The review is requested for the reason(s) stated below:

§103 Rejection of the Claims

Claims 1-11, 13, 14, and 16-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yarin et al. (U.S. Patent No. 6,294,999) in view of LaPorte et al. (U.S. Patent Application Publication No. 2005/0182389). Appellant respectfully traverses this rejection. No *prima facie* case of obviousness presently exists for these claims because there would be no motivation to combine Yarin et al. with LaPorte et al., as explained below.

The Final Office Action (hereinafter, “the Office Action”) at page 3 admits that “Yarin . . . fails to expressly teach a medication storage, therapy, and consumption management system, comprising: an implantable device configured to implantably electrically monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device.” However, the Office Action at page 3 contends that “LaPorte teaches a medication storage, therapy, and consumption management system, comprising: an implantable device configured to implantably electrically monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device”. The Office Action further contends at page 3 that “[o]ne of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Yarin with the teachings of LaPorte with the motivation that therapeutic substance therapy in conjunction with the activities

and information obtained by an implanted medical device is an important consideration in the overall treatment of a patient".

Yarin et al. relates to a *completely external, non-ambulatory system*. That is, the Smart Tray 12 of Yarin et al. is an externally disposed medication dispenser, and the appliances listed in Yarin et al. with which the Smart Tray 12 can communicate are external devices including "personal computers 22a, Web TVs 22b, weight scales 22c, refrigerators 22d, exercise devices 22e, and scanners 22f." (Yarin et al. at col. 5, lines 53-54.) The Smart Tray 12 further includes "a receptacle that is configured to removably receive and interact with various objects . . . [such as] blood pressure monitors, thermometers, pagers, glucometers, prothrombin and coagulation monitors." (Yarin et al. at col. 6, lines 39-44.) Again, all the listed devices intended to be used with the Smart Tray 12 of Yarin et al. are external devices. Yarin et al. states that "[a] Smart Tray according to the present invention passively and unobtrusively facilitates monitoring patient compliance with medication treatment regimens." (Yarin et al. at col. 9, lines 63-65.) There is no description in Yarin et al. related to use with internal devices, as admitted by the Office Action.

In contrast, LaPorte et al. relates to an *ambulatory, internal system*. LaPorte et al. describes a "device [that] delivers a therapeutic substance to the patient *while allowing the patient to remain mobile*." (LaPorte et al. at page 1, paragraph [0007] (Emphasis added.)) LaPorte et al. further states that "a medical therapy system includ[es] an implanted medical device 30 and a patch 32 for attachment to the skin of a patient." (LaPorte et al. at page 2, paragraph [0041].)

There is simply no motivation to combine the *non-ambulatory system* of Yarin et al. with the *ambulatory system* of LaPorte et al. LaPorte et al. relates to a system that *allows the patient to remain mobile* while delivering a therapeutic substance. Yarin et al. relates to an *external, non-ambulatory system for passively and unobtrusively facilitating monitoring of patient compliance with medication treatment regimens*. One of ordinary skill in the art would not look to the ambulatory system of LaPorte et al. to modify the non-ambulatory system of Yarin et al. In fact, Yarin et al. teaches away from being combined with LaPorte et al. and vice versa. There is simply no way to *passively and unobtrusively monitor patient compliance with medication treatment regimens using an implanted device*, nor is there any way to *allow the patient to*

remain mobile while delivering a therapeutic substance using the external, home-based Smart Tray system of Yarin et al. Appellant submits that, short of improper hindsight reconstruction, there is no reason and no objective motivation to combine the passive, unobtrusive Yarin et al. medication monitoring system with the mobile medical therapy system of LaPorte et al. The Office Action at page 9 goes on to contend that “any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning” and that “such a reconstruction is proper” if it “does not include knowledge gleaned only from the applicant’s disclosure”. However, short of improper hindsight reconstruction of Appellant’s claims, one of ordinary skill would not look to the *internal system* of LaPorte et al. to modify the *completely external system* of Yarin et al.

The Office Action at page 9 contends that “the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” However, the Office Action stops there and does not then go on to offer any possible motivation for the proposed combination, presumably relying on the contention at page 3 of the Office Action that “the motivation that therapeutic substance therapy in conjunction with the activities and information obtained by an implanted medical device is an important consideration in the overall treatment of a patient”. Contending that something is an “important consideration” does not amount to an objective motivation and is nothing more than a baseless statement. While the Appellant appreciates that the Examiner recognizes that obviousness can only be established where there is some teaching, suggestion, or motivation to combine the references in the manner suggested, Appellant takes the Office Action’s silence as to actual motivation as further evidence that no objective motivation exists for the combination of Yarin et al. and LaPorte et al. proposed by the Office Action.

Even assuming, for the sake of argument, that the references were combined in the manner proposed by the Office Action, the proposed combination would not function. There is no indication in Yarin et al. that the Smart Tray 12 is configured to communicate with an implanted sensor. In fact, Yarin et al. includes “a receptacle that is configured to removably receive and interact with various objects . . . [such as] blood pressure monitors, thermometers,

pagers, glucometers, prothrombin and coagulation monitors.” (Yarin et al. at col. 6, lines 39-44.)

Of course, the implanted device of LaPorte et al. would be incapable of being received within such a receptacle of Yarin et al. While Yarin et al. does state that wireless communications may be used for the devices of Figs 1 and 2 (*see* Yarin et al. at col. 6, lines 1-5; and Figs 1 and 2), none of the devices shown or described by Yarin et al. are *implanted* within a patient. Moreover, wireless communication of the *external, non-ambulatory* Yarin et al. Smart Tray with a stationary weight scale, for instance, is not akin to wirelessly communicating with a mobile implanted device within a patient. The present application solves numerous problems and technical challenges to allow communication between an external containment unit and an implantable device that Yarin et al. and LaPorte et al., either alone or in combination, do not even address. The Office Action fails to grasp this point, as is evidenced by the contention of the Office Action at page 9 that “Yarin is only distinguished from LaPorte in the sense that it communicates with an external device.” For instance, Yarin et al. includes no description related to a structure, module, etc. for proximity detection and synchronization of the Smart Tray of Yarin et al. with any mobile, implanted device, such as the implanted device of LaPorte et al., in order to allow for communication therebetween, as would be necessary for the proposed modified device to function. Likewise, LaPorte et al. includes no description related to a structure, module, etc. for proximity detection and synchronization of the implanted device of LaPorte et al. with the external Smart Tray of Yarin et al., in order to allow for communication therebetween, as would be necessary for the proposed modified device to function. As such, even if the references were combined in the manner suggested by the Office Action, the resulting combination would be unable to overcome the numerous problems and technical challenges identified above and would, therefore, not function to provide communication between the non-ambulatory Smart Tray of Yarin et al. and the ambulatory implanted device of LaPorte et al.

In sum, because the proposed combination of references lacks any objective motivation for their combination by one of ordinary skill in the art, and because such combination is apparently non-functional, Appellant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Appellant respectfully requests reversal of this rejection of these claims.

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CONCLUSION

Appellant respectfully submits that all of the pending claims are in condition for allowance, and such action is earnestly solicited. The Examiner is invited to telephone the below-signed attorney at (612) 359-3275 to discuss any questions which may remain with respect to the present application. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date July 1, 2009

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 1st day of July 2009.

Kate Gannon

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